



PATENT
Attorney Docket No. EXT-048

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Shuber
SERIAL NO.: 09/755,004 GROUP NO.: 1637
FILING DATE: January 5, 2001 EXAMINER: S. Chunduru
TITLE: Methods for Detecting, Grading or Monitoring an H. pylori Infection

Commissioner for Patents
Washington, D.C. 20231

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

- ☐ the requisite Statement is below, AND
☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

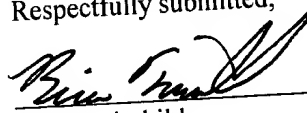
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

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Respectfully submitted,



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SHEET 1 OF 1

FORM PTO - 1449

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-048

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GROUP: 1631600/2900

OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C15 B��langer et al., "Rapid Detection of <i>Clostridium difficile</i> in Feces by Real-Time PCR," <u>J. Clin. Microbiol.</u> , 41(2): 730-734 (Feb. 2003).
	C16 Bickley et al., "Evaluation of the polymerase chain reaction for detecting the urease C gene of <i>Helicobacter pylori</i> in gastric biopsy samples and dental plaque," <u>J. Med. Microbiol.</u> , 39(5): 338-344 (1993).
	C17 Bravos et al., "Accurate Diagnosis of <i>Helicobacter pylori</i> ," <u>Gastroenterology Clinics of North America</u> , 29(4): 925-929 (Dec. 2000).
	C18 Johnston et al., "Evaluation of Three Commercial Assays for Detection of <i>Giardia</i> and <i>Cryptosporidium</i> Organisms in Fecal Specimens," <u>J. Clin. Microbiol.</u> , 41(2): 623-626 (Feb. 2003).
	C19 Kawamata et al., "Nested-Polymerase Chain Reaction for the Detection of <i>Helicobacter pylori</i> Infection with Novel Primers Designed by Sequence Analysis of Urease A Gene in Clinically Isolated Bacterial Strains," <u>Biochem. And Biophys. Research Comm.</u> , 219(1): 266-272 (Feb. 1996).
	C20 Mapstone et al., "Identification of <i>Helicobacter pylori</i> DNA in the mouths and stomachs of patients with gastritis using PCR," <u>J. Clin. Pathol.</u> , 46(6): 540-543 (Jun. 1993).
	C21 Monteiro, et al., "Complex Polysaccharides as PCR Inhibitors in Feces: <i>Helicobacter pylori</i> Model," <u>J. Clin. Microbiol.</u> , 35(4): 995-998 (Apr. 1997).
	C22 Nagashima et al., "Application of New Primer-Enzyme Combinations to Terminal Restriction Fragment Length Polymorphism Profiling of Bacterial Populations in Human Feces," <u>Applied and Environ. Microbiol.</u> , 69(2): 1251-1262 (Feb. 2003).
	C23 Osaki, et al., "Detection of <i>Helicobacter pylori</i> in Fecal Samples of Gnotobiotic Mice Infected with <i>H. pylori</i> by an Immunomagnetic-Bead Separation Technique," <u>J. Clin. Microbiol.</u> , 36(1): 321-323 (Jan. 1998).
	C24 Shuber et al., "Accurate, Noninvasive Detection of <i>Helicobacter pylori</i> DNA from Stool Samples: Potential Usefulness for Monitoring Treatment," <u>J. Clin. Microbiol.</u> , 40(1): 262-264 (Jan. 2002).
	C25 Song et al., " <i>Helicobacter pylori</i> in Dental Plaque: A Comparison of Different PCR Primer Sets," <u>Digestive Dis. and Sci.</u> , 44(3): 479-484 (Mar. 1999).
	C26 Uribe et al., "Sensitive Detection of <i>Helicobacter pylori</i> in Gastric Aspirates by Polymerase Chain Reaction," <u>The Journal of the Japanese Association for Infectious Diseases</u> , 72(2): 114-122 (Feb. 1998).
	C27 Watanabe, et al., "Detection of <i>Helicobacter pylori</i> Gene by Means of Immunomagnetic Separation-Based Polymerase Chain Reaction in F��ces," <u>Scandinavian Journal of Gastroenterology</u> , 33(11): 1140-1143 (1998).
	C28 Weiss et al., "Comparison of PCR and Other Diagnostic Techniques for Detection of <i>Helicobacter pylori</i> Infection in Dyspeptic Patients," <u>J. Clin. Microbiol.</u> , 32(7): 1663-1668 (Jul. 1994).
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C29	Westblom, et al., "Diagnosis of <i>Helicobacter pylori</i> Infection by means of a Polymerase Chain Reaction Assay for Gastric Juice Aspirates," <u>Clin. Infectious Dis.</u> , <u>16(3)</u> : 367-371 (Mar. 1993).
	C30	Yoshida et al., "Use of a Gastric Juice-Based PCR Assay To Detect <i>Helicobacter pylori</i> Infection in Culture-Negative Patients," <u>J. Clin. Microbiol.</u> , <u>36(1)</u> : 317-320 (Jan. 1998).
EXAMINER		DATE CONSIDERED

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